

## Supplement to Appendix A

### GUIDELINES FOR DRAFTING THE RESEARCH PLAN

In order to assist in the drafting of an appropriate Research Plan and to facilitate its processing and approval at NIH, the following supplement has been adopted.

**Use as many additional pages as are necessary in order to respond fully, and responses shall be consistent with the numbering below. These guidelines are an incorporated part of this CRADA.**

#### 1. GOAL OF THIS CRADA:

Identify (three to four sentences) the research goal(s) of this CRADA, including the respective research goals of the NIH and Collaborator Principal Investigators (PIs). Explain why this project is important scientifically.

#### 2. DETAILED DESCRIPTION OF THE RESEARCH PLAN:

The primary purpose of this Research Plan is to permit careful monitoring of CRADA research projects by scientific and division directors of NIH institutes, centers, and divisions (ICDs). An additional purpose for the Research Plan is established by the Federal Technology Transfer Act of 1986 (FTTA). Under the FTTA, the Parties' obligations to each other in such areas as confidentiality and patent rights extend only to "*specified research or development efforts*." This statutory limitation will create the boundaries for license rights to inventions made under the CRADA. Accordingly, appropriate care should be taken in drafting this Research Plan carefully and completely. The field(s) of use to which Article 8 of this CRADA pertains will be limited to the specified research or development efforts in view of the foregoing research goals. The Collaborator further should bear in mind that, although insubstantial changes in this Research Plan may be made by mutual consent of the PIs under Article 3.2, substantial changes will require formal amendment under Article 13.6 in order to maintain entitlement to invention rights. As a result, absent *compelling* justification for a failure to make the original Research Plan complete, amendments will *not* be made retroactive.

Therefore, please provide a description (two to five pages) of the intended Research Plan in sufficient detail to permit reviewers of the CRADA to evaluate the scientific merit of the proposed collaboration. The Research Plan should be described in detail in terms of *specific research projects* not in terms of a general research program or research goals. Contemplated initial and subsequent projects should be summarized along with estimated time periods for their completion. These projects may be described sequentially in distinct phases contingent upon the success of earlier phases. Important methodological considerations should be noted, and citations to pertinent literature reference may be helpful.

#### 3. RESPECTIVE CONTRIBUTIONS OF THE PARTIES:

Under Paragraph 5 of the NIH "Policy Statement," CRADAs are authorized only with collaborators who will make a significant intellectual contribution to the research project undertaken, or who will contribute essential research materials or technical resources not otherwise reasonably available to NIH. **CRADAs are not viewed by NIH as a general funding source or as a mechanism for sponsored research.** Therefore, the Research Plan *must* indicate clearly that a true intellectual collaboration will take place, i.e., essential materials or technical resources are involved. With regard to the detailed research plan described above, identify, in detail by Party and by Principal Investigator

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the respective contributions of research, development, analysis, expertise, research materials, time, etc. to be committed to the various specified research projects and their component steps. In conjunction, in Appendix C, please list those financial and staffing contributions as detailed in the Research Plan.

**4. ABSTRACT OF THE RESEARCH PLAN FOR PUBLIC RELEASE:**

In order to fulfill its obligations regarding NIH activities to the public, to Congress, and to the scientific community, NIH intends to make an abstract of this Research Plan available upon request. To protect the legitimate concerns of the Collaborator as to its research agenda, the Collaborator is requested to assist in and carefully review this abstract. Signature of this CRADA by the Collaborator shall be deemed to be agreement by the Collaborator that NIH may disclose this abstract publicly.

**5. RELATED CRADAs AND/OR MTA-CRADAs:**

The Collaborator should identify by Title, Principal Investigator, and Institute all other CRADAs and/or MTA-CRADAs that it has with NIH. The NIH Principal Investigator should similarly identify all CRADAs and/or MTA-CRADAs that his or her laboratory has with this or any other Collaborator.

**6. RELATED MTAs AND/OR MTA-CRADAs:**

The NIH Principal Investigator must review his or her laboratory files carefully and attach to the clearance form for this CRADA any material transfer agreements (*including MTA-CRADAs*) from any source that provided research materials used in earlier projects that relate directly or indirectly to this CRADA, *or* that provided research materials used to develop any materials to be studied or utilized in this CRADA. The ICD Technology Development Coordinator should similarly review any central material transfer agreement files and attach relevant agreements.

**7. RELATED PATENT APPLICATIONS AND PATENTS:**

The NIH Principal Investigator and his or her Technology Development Coordinator should identify by title and serial number any ICD patent applications and patents that are directly or indirectly related to the subject matter of this CRADA.

**8. AVOIDANCE OF CONFLICT OF INTERESTS AND ASSURANCE OF FAIR ACCESS:**

NIH has implemented the FTTA with strict attention to Federal conflict of interest and ethic laws, as well as various Department of Health and Human Services (DHHS) and NIH regulations. Additionally, the Public Health Service (PHS) has issued guidelines for PHS agencies in order to assure fair access to our laboratories and consideration for CRADAs. Completion and signature certification of the conflict of interest disclosure and fair access assurance form by the NIH Principal Investigator and ICD Ethics Officer is *mandatory* prior to review of a proposed CRADA by the CRADA Subcommittee.